

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	MDL No. 2875
THIS DOCUMENT RELATES TO ALL CASES	HON. ROBERT B. KUGLER CIVIL NO. 19-2875 (RBK)

**CERTIFICATION OF ROSEMARIE RIDDELL BOGDAN IN SUPPORT OF
PLAINTIFFS' DAUBERT MOTION TO EXCLUDE TESTIMONY OF GEORGE
JOHNSON, Ph.D.**

Rosemarie Riddell Bogdan, hereby certifies as follows:

1. I am an attorney at law within the State of New York and a partner with the law firm of Martin, Harding & Mazzotti, LLP, and serve as Court-appointed Plaintiffs' Steering Committee Counsel. I am fully familiar with the facts and circumstances of these actions. I make this Certification in support of Plaintiffs' motion to exclude the testimony of George Johnson, Ph.D.
2. Attached hereto as **Exhibit A** is a true and accurate copy of the European Medicine Agency, February 14, 2019, Committee for Medicinal Products for Human Use (CHMP) Assessment Report, Referral under Article, Angiotensin-II-receptor antagonists (sartans) containing a tetrazole group.
3. Attached hereto as **Exhibit B** is a true and accurate copy of Day 1 (October 4, 2021) Deposition Transcript of George Johnson.
4. Attached hereto as **Exhibit C** is a true and accurate copy of George Johnson, Ph.D.'s Amended Report.

5. Attached hereto as **Exhibit D** is a true and accurate copy of the Control of Nitrosamine Impurities in Human Drugs, Guidance for Industry, FDA, Center for Drug Evaluation and Research (CDER), February 2021.

6. Attached hereto as **Exhibit E** is a true and accurate copy of ICH M7(R1) FDA Guidance for Industry: Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals To Limit Potential Carcinogenic Risk (March 2018).

7. Attached hereto as **Exhibit F** is a true and accurate copy of Peto (1991) *Effects on 4080 Rats of Chronic Ingestion of N-nitrosodiethylamine or N-nitrosodimethylamine: A Detailed Dose Response Study* Cancer Research.

8. Attached hereto as **Exhibit G** are true and accurate copies of the Carcinogenicity Database Reports for NDMA and NDEA.

9. Attached hereto as **Exhibit H** is a true and accurate copy of Johnson, et. al, *Permitted daily exposure limits for noteworthy N-nitrosamines*, May 2021.

10. Attached hereto as **Exhibit I** is a true and accurate copy of U.S. Food and Drug Administration, Laboratory Analysis of valsartan products, 5/2/2019 at <https://www.fda.gov/drugs/drug-safety-and-availability/laboratory-analysis-valsartan-products>.

11. Attached hereto as **Exhibit J** is a true and accurate copy of Day 2 (October 5, 2021) Deposition Transcript of George Johnson.

12. Attached hereto as **Exhibit K** is a true and accurate copy of FDA General Advice to pharmaceutical companies making angiotensin II receptor blockers, (ARB) drug product (DP) regarding the presence of one or more toxic impurities in some ARB drugs (i.e., Valsartan).

13. Attached hereto as **Exhibit L** is a true and accurate copy of EMA Assessment Report, 2020.

14. Attached hereto as **Exhibit M** is a true and accurate copy of Health Canada – Q&A on nitrosamine impurities (2020), using linear extrapolation TD50.
15. Attached hereto as **Exhibit N** is a true and accurate copy of TGA (Australia) – nitroso compounds in ‘sartan’ medicines (2019).
16. Attached hereto as **Exhibit O** is a true and accurate copy of PMDA (Japan) – Control of Nitrosamine Impurities in sartan drugs (2021).
17. Attached hereto as **Exhibit P** is a true and accurate copy of Torrent Valsartan NDMA test results; TORRENT-MDL2875-00366172 and for NDEA: TORRENT-MDL2875-00133890.
18. Attached hereto as **Exhibit Q** is a true and accurate copy of ZHP/Solco test results, SOLCO000028261.
19. Attached hereto as **Exhibit R** is a true and accurate copy of Kaina, et. al, *Transfection and expression of human 06-methylguanine-DNA methyltransferase (MGMT) cDNA in Chinese hamster cells; the role of MGMT in protection against the genotoxic effects of alkylating agents* (1991).
20. Attached hereto as **Exhibit S** is a true and accurate copy of Kaina, et. al, *Contribution of 06-alkylguanine and N-alkylpurines to the formation of sister chromatid exchanges, chromosomal aberrations, and gene mutations; new insights gained from studies of genetically engineered mammalian cell lines* (1993).
21. Attached hereto as **Exhibit T** is a true and accurate copy of DeStefani E, Boffetta P, Mendilaharsu M et al. Dietary nitrosamines, heterocyclic amines, and risk of gastric cancer: A case-control study in Uruguay. *Nutrition and Cancer* (1998).

22. Attached hereto as **Exhibit U** is a true and accurate copy of Pobel D, Riboli E, Cornée J et al. Nitrosamine, nitrate and nitrite in relation to gastric cancer: a case-control study in Marseille, France. Eur J Epidemiol (1995).

23. Attached hereto as **Exhibit V** is a true and accurate copy of Larsson SC, Bergkvist L, Wolk A. Processed meat consumption, dietary nitrosamines and stomach cancer risk in a cohort of Swedish women. Int J Cancer (2006).

24. Attached hereto as **Exhibit W** is a true and accurate copy of La Vecchia, et al, Nitrosamine intake and gastric cancer risk. European Journal of Cancer Prevention, Volume 4 (1995).

25. Attached hereto as **Exhibit X** is a true and accurate copy of De Stefani E, et al., Dietary nitrosodiemethylamine and the risk of lung cancer: A case-control study from Uruguay. Cancer Epidemiology Biomarkers and Prevention (1996).

26. Attached hereto as **Exhibit Y** is a true and accurate copy of Hidajat M, et al., Lifetime exposure to rubber dusts, fumes and N-nitrosamines and cancer mortality in a cohort of British rubber workers with 49 years follow-up, Occupational and Environmental Medicine (2019).

27. Attached hereto as **Exhibit Z** is a true and accurate copy of *In re Tylenol (Acetaminophen) Mktg.*, 2016 U.S. Dist. LEXIS 92334; 2016 WL 3854534 (E.D. Pa., 2016).

28. Attached hereto as **Exhibit AA** is a true and accurate copy of *In re Zicam Cold Remedy Mktg., Sales, Practices & Prods. Liab. Litig.*, 2011 U.S. Dist. LEXIS 20356; 2011 WL 798898 (D. C. Az., 2011).

29. Attached hereto as **Exhibit BB** is a true and accurate copy of *Koninklijke Philips N.V. v. Zoll Lifecor Corp.*, 2017 U.S. Dist. LEXIS 116337 (W.D. Pa., 2017).

30. Attached hereto as **Exhibit CC** is a true and accurate copy of *Sakolsky v. Genie Indus.*, 2021 U.S. Dist. LEXIS 155821; 2021 WL 3661398 (D.N.J., 2021).

MARTIN, HARDING & MAZZOTTI LLP
Attorneys for Plaintiffs

By: /s/ Rosemarie Riddell Bogdan

Dated: November 1, 2021

CERTIFICATE OF SERVICE

I hereby certify that on November 1, 2021, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notifications of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/ Rosemarie Riddell Bogdan

Rosemarie Riddell Bogdan